REMARKS

Applicants confirm the provisional election of species as set forth in the response filed September 28, 2005.

However, applicants remind the examiner that upon allowance of a generic claim, applicants are entitled to a reasonable number of species and, thus, applicant requests that the withdrawn claims are permitted to remain pending until examination is complete.

Reconsideration of the previous rejection of claims 1-7, 9-14 and 17-19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent 6,632,461 is respectfully requested in view of the attached Terminal Disclaimer and fee therefore.

As the Terminal Disclaimer adopts the language suggested by the Patent Office for overcoming obviousness-type double patenting, it is respectfully submitted that the submission of the Terminal Disclaimer moots this rejection and withdrawal of this rejection is respectfully requested.

Reconsideration of the previous rejection of claims 1-7, 9-14 and 17-19 under 35 U.S.C. §112, 1st paragraph, is respectfully requested. The examiner has conceded that the specification enables treatment of particular conditions and symptoms in animals, including humans, as recited in claim 1 of now issued U.S. Patent 6,632,461.

In rejecting the claims as being based on a non-enabling specification (e.g., allegedly insufficient to support the breadth of the claims), the examiner alleges that such non-enablement is due to "undue experimentation," citing In re Wands, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988).

However, such authority is inapposite to the presently claimed methods and the enablement of the specification.

In In re Wands, the invention relied on a particular microorganism as identified in the specification, but for which no deposit was made. Thus, the question before the court in In re Wands was whether one of ordinary skill in the art, having an identification of the microorganism, but without a deposit thereof, could, nonetheless, practice the invention.

This is not the case here. Here, no microorganism is involved in the methods of treatment of the present claims. Rather, applicant claims a method comprising two steps (a) withholding all food (from the patient) for at least five days, except for the tropical root crops; and (b) feeding a concentrated form of tropical root crops for at least the five day period.

There is clearly no undue experimentation in the claimed process.

For example, the step of "withholding all food for at least five days" would be clearly understood by those skilled in the art to which the invention pertains without further exemplification or description in the specification.

Furthermore, the second step of "feeding a concentrated form of tropical root crops for at least the five day period" would also be understood by those having ordinary skill in the art. The

examiner has not suggested how any undue experimentation would be required in connection with the claimed method.

Rather, it appears that the examiner's approach to the invention is whether it is "safe and effective" in treating animal patients. Such an approach is surely beyond the authority vested in the United States Patent and Trademark Office. As stated by the Court of Customs and Patent Appeals in In re Anthony, 162 USPQ 594 (1969), where the court stated, at 603-04 that:

> "The patent statutes do not establish 'safety' as a criteria for patentability of any of the statutory classes of patentable subject matter mentioned in Section 101."

The Court continued:

> "And Congress has given the responsibility to the FDA, not to the Patent Office, to determine, in the first instance, whether drugs are sufficiently safe for use, if they can be introduced in the commercial market, under the conditions prescribed, recommended, or suggested under the proposed labeling thereof" (citing In re Hartop, 135 USPQ 419 (CCPA 1962).

The Court continued:

> "We believe that Congress had recognized this problem and has clearly expressed its intent to give statutory authority and responsibility in this area to Federal agencies different than that given to the Patent Office."

Moreover, the examiner's comment appearing at the top of page 6 of the previous Office Action is telling as to the scope to be granted to the applicant for this invention:

> "Moreover, it should be noted that the state of the prior art at the time the invention was filed did not recognize a method of treating any and/or all chronic diseases, conditions and symptoms in animals by any method including the method instantly claimed . . . . Thus, the art is silent regarding the efficacy of applicant's method of treating any and/or all chronic diseases, conditions and symptoms in animals comprising a) withholding all food for at least five days, except for at least five days,

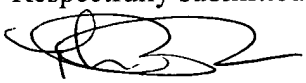
except for tropical root crops b) and feeding a concentrated form of any and/or all tropical root for a period of at least five days."

This comment demonstrates that there is no prior art "hemming in" applicant's claimed subject matter which is indicative of "a pioneer patent," but, rather than requiring undue experimentation to carry out the claimed method, the examiner is really expressing his concern as to the "efficacy" (i.e., "the power to produce an effect") on the patient, which the courts have relegated to the FDA, not the United States Patent and Trademark Office.

Applicant reiterates the claimed subject matter, though it should be apparent to the examiner, that applicants are not claiming a "cure" for the chronic diseases, conditions and symptoms, but, rather, a method of "treatment." As such, the specification clearly enables the scope of the claimed invention to such methods of treatment.

For all the foregoing reasons, withdrawal of all rejections and passage of the application to issue are respectfully requested.

Respectfully submitted,



TPP/mat
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Attachment:
Terminal Disclaimer

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